

U.S. CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814

Statement of Commissioner Robert S. Adler Regarding the Petition of Joseph Ertl, Inc., for an Exemption From the Lead Content Limits for Certain Components of Its Ride-On Pedal Tractors

April 25, 2012

On March 27, 2012, the Consumer Product Safety Commission unanimously voted to grant an exception from our lead content limit of 100 parts per million (ppm) to Joseph L. Ertl, Inc., (hereinafter, "Ertl" or "petitioner") for the aluminum alloy parts of its diecast, ride-on pedal tractors. I was pleased to join in this vote, which I believe represented a thoughtful and measured approach to implementing the statutory mandate that governs the Commission's regulation of lead. That said, I feel it useful to add a few words to explain what I think our vote represents and what it does not.

Background

Lead is a powerful neurotoxin that accumulates over time. Even low levels of lead are widely associated with learning disabilities, decreased growth, hyperactivity, impaired hearing and brain damage. The regulation of lead has been a controversial topic almost since the day the Consumer Product Safety Commission began operations. Over the years, the Commission has struggled with lead issues, including lead in paint, lead in candles, and lead in children's products. And, as safety studies have become more refined, our understanding of lead's hazards has expanded, leading to greater restrictions on its use.

In fact, the history of lead regulation has consistently shown that each time a standard for lead has been set, new evidence has surfaced that demonstrates that even lower levels of lead can harm consumers, especially young children. Children have proven to be more vulnerable to lead's effects than adults for several reasons: they tend to mouth things in

¹ I shall use the terms "exception" and "exemption" interchangeably throughout this statement.

the environment, their gastrointestinal tracts tend to absorb more chemicals than adults, and their developing nervous systems are thought to be more vulnerable to lead than adult systems.² In fact, virtually all experts have concluded that there is no known "safe" level of lead. The most that can be said is that below certain lead levels, science currently cannot measure adverse health effects. The lack of measurable adverse effects at these low exposure levels, however, does not mean that no such effects occur.

More broadly, one should note that lead hazards continue to plague our society. Despite major strides towards reducing lead exposure in young children in recent years, the United States still has an unacceptably large number of children with elevated blood lead levels.³ To be sure, most of the problem relates to matters outside of the CPSC's jurisdiction, such as lead paint in older houses and apartments, or toxic dirt in inner city playgrounds and neighborhoods. But, the CPSC still bears a significant measure of responsibility given the ubiquity of children's products and the fact that even small amounts of lead add to the total lead load in children's bodies.

Based on the most current evidence available at the time, Congress, in the Consumer Product Safety Improvement Act of 2008 (CPSIA), took the regulation of lead to perhaps its most stringent level. In section 101(a) of the CPSIA, Congress set progressively lower lead limits in children's products from 600 ppm to 300 ppm by statute. Congress then lowered the lead content in children's products to no more than 100 ppm unless the Commission determined that such a limit was not "technologically feasible." After analyzing the available economic data and providing an open hearing for members of the public, the Commission staff determined that most manufacturers would find it technologically feasible to meet this standard. Accordingly, the Commission, by majority vote on July 13, 2011, approved the staff's determination, thereby complying with the statute's direction to lower the lead limit to 100 ppm.

Exemptions from the Lead Limits

When Congress debated the CPSIA in 2008, a number of manufacturers insisted that they would have great difficulty meeting the new lead limits. In response, Congress first gave manufacturers a six-month grace period before requiring a 600 ppm lead limit for children's products and then an additional six-month period before moving the limit to 300 ppm. In addition, Congress provided statutory exemptions from the lead requirements for certain children's electronic devices and for inaccessible component parts of children's products. Finally, Congress wrote an exclusion provision for products

² For an expanded discussion of lead hazards, I refer the reader to my statement on lead, *Statement on Lead Regulation Under the CPSIA* at http://www.cpsc.gov/pr/adler01222010.pdf (January 22, 2010).

³ See, e.g., Los Angeles Times, "Unsafe Levels of Lead Still Found in California Youths," http://articles.latimes.com/2012/feb/19/local/la-me-lead-poisoning-20120219; Environmental Protection Agency, "Basic Information on Lead," http://www.epa.gov/lead/pubs/leadinfo.htm; and "Lead Poisoning," http://en.wikipedia.org/wiki/Lead_poisoning.

where the Commission determined such products would not produce "any" absorption of lead into the human body nor have any other adverse impact on public health or safety.⁴

In fact, the latter exemption proved too stringent to accommodate the legitimate concerns of some manufacturers. As CPSC staff repeatedly pointed out when the Commission considered various requests by manufacturers for exemptions from the lead standard, virtually all products that contain lead leach some of this heavy metal, even if only infinitesimal amounts, that could be absorbed by a human body. In short, the universe of products eligible for an exemption under this section probably constituted a null set. Needless to say, this caused a number of manufacturers to voice objections to the lack of a meaningful exemption provision in the law.

Congress acknowledged these concerns when it amended the CPSIA by enacting Public Law (P.L.) 112-28. Under this new law, Congress added a "functional purpose" test for exempting products containing lead. As a long-time supporter of such a test, I welcomed Congress's action. Although I have some misgivings about the precise language in the functional purpose test of P.L. 112-28,⁵ I consider it generally to be a thoughtful and balanced approach to regulating lead. Under this test, the Commission must make three findings in order to grant an exemption from the lead content limit to a children's product:

- (1) The product requires the inclusion of lead because it is not practicable or technologically feasible to manufacture the product by removing the lead or by making it inaccessible,
- (2) The product is not likely to be placed in a child's mouth or ingested under reasonably foreseeable use and abuse of the product, and

_

⁴ Specifically, Congress, in section 101(b) of CPSIA, provided that:

⁽¹⁾ The Commission may, by regulation, exclude a specific product or material from the [banned lead levels] if the Commission, after notice and a hearing, determines on the basis of the best-available objective, peer-reviewed, scientific evidence that lead in such product or material will neither –

A. Result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking or other children's activities, and the aging of the product; nor

B. Have any other adverse impact on public health or safety.

⁵ What causes my misgivings is how Congress defined the term "no measurable adverse effect on public health or safety." For purposes of our granting exemptions under the new law, the term means that there can be "no measurable increase in the blood lead levels of a child" from exposure to the product. Although I see no particular problem with this standard given the current state of science, I fear two possible unintended outcomes in the future. First, but quite unlikely, it is conceivable that small scientifically unmeasurable amounts of lead might one day be found to produce harmful health effects in children. In such a case, the test would be too lax. Second, and more likely, there may come a time when infinitesimally small changes in blood lead levels carrying no negative health effects might be measurable in a child, thereby triggering an unnecessary rejection of a manufacturer's request for a product's exemption from the lead standard.

(3) An exception for the product will have no measurable adverse effect on public health or safety, taking into account reasonably foreseeable use and abuse of the product.⁶

The Ertl Petition

On September 29, 2011, under the newly-enacted functional purpose test, Ertl requested an exemption from the 100 ppm lead content limit for children's products for its die-cast ride-on pedal tractors. The firm claimed that it was not practicable for it to meet the lead content limit of 100 ppm for the aluminum alloy components of these tractors. As a small manufacturer with 2011 sales of approximately \$1 million, Ertl argued that being forced to purchase complying alloyed metals would, in effect, force it to exit the farm toy business. The company claimed, however, that it could meet an upper limit of 300 ppm through careful monitoring of its purchases.

With respect to the second prong of the functional purpose test, based on its experience with its customers, the company claimed that a child would be unlikely to extensively touch the areas of the tractor with the metal casting. Rather, the child would typically sit on the seat and hold the plastic steering wheel, neither of which would expose the child to the metal casting. Moreover, although not arguing that the powder coating surface on the metal casting would render the tractor compliant with the lead standard, the company noted that the coating would tend to reduce contact between the metal casting and the child, thereby lessening the child's exposure to the metal alloy.

Finally, with respect to the question of whether the metal alloys in its products would have a measurable adverse public health effect, the company pleaded lack of financial resources to provide an answer with scientific certainty. Instead, the company referenced the testing that it had subjected its products to over the years – and which it would use for future production – to demonstrate that it could consistently meet an upper limit of 300 ppm.

Staff Analysis of the Ertl Petition

Although the company did not submit extensive human factors data nor any significant scientific data regarding the health risks of its product, CPSC staff did its best to fill in the gaps in the company's exemption request. Frankly, these gaps concern me and make me reluctant to support similar requests from companies with the financial resources to

⁶ Section 101(b)(1)(A)(i)-(iii) of P.L. 112-28.

⁷ In particular, the company indicated that aluminum alloys with less than 100 ppm would entail its having to purchase special "heat batch" materials, with a minimum order size of 120,000 pounds, or roughly seven years worth of material, requiring about 15 percent of its yearly sales just to purchase the materials.

⁸ Section 101(b)(3) of the CPSIA, as a matter of law, bars consideration of paint as a barrier that would render lead in the substrate of a product inaccessible to a child.

provide better data. That said, I applaud the proactive staff steps to deal with the request from this financially-limited company.

Based on its analysis, staff concluded that, although it was technologically feasible for Ertl to make tractors to the 100 ppm standard, the added costs the company would face in doing so made it impracticable to meet the standard. Accordingly, staff concluded that Ertl met (or "failed," depending on one's perspective) the practicability requirements for an exemption.

With respect to the issue of a child mouthing or ingesting lead from the component parts in question, staff agreed with the petitioner's claim that, notwithstanding occasional behaviors that might result in a child's exposure to the lead-containing components, these parts are too large for a child to place in his or her mouth. Moreover, based on staff's analysis, they agreed with the company's claim that users of the tractors are of an age whereby few of them would be likely to engage in mouthing behaviors for the toys they use.

Staff's consideration of the last finding required in P.L. 112-28 – whether there would be a measurable adverse effect on public health – gives me some concern, although, on balance, I accept their judgment. I start with the fact that the company submitted no evidence regarding whether there would be any measurable adverse effect on public health. I further note that staff never acquired an Ertl tractor for testing to confirm that a child's exposure to the product would result in no measurable increase in the child's blood lead level.

What staff did instead was to look to past studies of wipe tests on other products with lead content more than 100 ppm. In particular, staff pointed to data from previous agency tests on metal jewelry and polyvinyl chloride products where lead contents ranged from 100 ppm up to 100,000 ppm (equivalent to 10 percent of the metal in the product). According to staff, even extremely high levels of lead showed transfers from a wipe test (the test that staff would use on an Ertl tractor) that averaged less than 0.02 micrograms (µg) per test. Accordingly, staff concluded that a similarly small amount of lead would be transferred from one of petitioner's products in such a test. Staff then cited a model from the Environmental Protection Agency (EPA) known as the "Integrated Exposure Uptake BioKinetic Model for Lead in Children" (IEUBK), to predict the likely added exposure to lead resulting from a child's playing with a tractor every day over a fairly long period of time. In applying the IEUBK model to the Ertl tractor, staff, to be conservative, assumed a higher exposure to lead than 0.02 micrograms:

Staff includes the estimate of the effect on the blood level of daily exposure to $0.6 \mu g/day$ to provide quantitative context to this analysis. If staff were to use the assumption that about half of the lead that might collect on the hands during the day would be transferred to the child's mouth during the day, it would follow that

about 1.2 μ g of lead could collect on a child's hands (*i.e.*, 0.6 μ g/ day transferred to the mouth), resulting in the theoretical change in blood lead level of 0.1 μ g/dL, a change that is not a measurable increase in the blood lead level.

Staff further stated that it expected that possible daily exposure to lead from the pedal tractor "would be very low, perhaps even nondetectable, using standard laboratory techniques." Based on this analysis, staff concluded that the total exposure would be so small that it would have no measurable adverse effect on public health.

Finally, staff pointed out that the tractors for which Ertl sought an exemption are similar to off-highway vehicles which Congress, in P.L. 112-28, exempted from the 100 ppm lead content limit and to bicycles and similar products for which Congress set a 300 ppm lead limit for their metal components, such as pedals. Given the similarities of products and the similarities of risk, it is, therefore, a short step to consider treating the petitioner's product in a similar fashion. Accordingly, staff recommended approval of the Ertl petition.

My Vote

Having consulted with CPSC staff on the matter and having carefully read the briefing package, I voted to approve the recommendation to grant this exemption request. I did so with some concern.

My concern is that staff's conclusion that exposure to the lead in an Ertl tractor might in theory be detectable raises the question whether future petitioners should submit actual test reports to demonstrate that no such result would occur. I say this because past petitioners for exemptions, for the most part, have provided such test reports and, as I understand it, there are a number of labs and toxicology consulting firms that can assist in providing such information at a relatively low cost. I strongly urge future petitioners to submit not just information regarding the amount of lead in their children's products, but also the exposure to this lead that children would likely face when using such products.

⁹ See, e.g., Petition for Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act, by Polaris Industries, American Suzuki Motor Corporation, Arctic Act, Inc. Kawasaki Motors Corp, U.S.S. American Honda Motor Co, Inc., and Yamaha Motor Corporation (January 27, 2009); Petition for Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act, by Motorcycle Industry Council (MIC) (January 28, 2009); Petition for Temporary Final Rule to Exclude a Class of Materials Under Section 101(b) of the Consumer Product Safety Improvement Act by Bicycle Product Suppliers Association (BPSA) (May 6, 2009); Section 101 Request for Lead Content Exclusion for Pen Part Components by David Baker, LLC, for the Writing Instrument Manufacturers Association (February 9, 2009); and Section 101 Request for Exclusion of a Material or Product; Request to Exempt Crystal Beads and Rhinestones by Jewelry Producers and Retailers, Fashion Jewelry Trade Association (FJTA), Manufacturing Jewelers and Suppliers of America (MJSA), Footwear Distributors and Retailers of America (FDRA), National Retail Federation (NRF), and United Dance Merchants of America (February 24, 2009).

That said, several points make me comfortable with the staff's recommendation regarding the Ertl petition.

- Totality of Factors: Staff analyzed this case carefully and made its recommendation based on the totality of the factors present in this case, including costs, financial circumstances of the company, the size of the company, its distribution pattern, consumer preferences, congressional exemptions for similar products, and the specific relief sought by the company. Moreover, staff concluded that the component parts covered by the petition would not likely be placed in a child's mouth or ingested (or extensively touched) because of their function and location on the product and the agency's familiarity with pedals and similar component parts of products such as bicycles and youth off-highway vehicles.
- The Company Will Continue to Meet a 300 ppm Lead Content Limit: The company submitted extensive test results that showed that it could meet the 300 ppm lead limit for its product. Ertl did not seek a complete exemption from the lead content limits, only an increase in permissible lead limits up to 300 ppm. Accordingly, our decision still requires the company to meet a very low lead limit. 10
- Ride-On Pedal Tractors are Similar to Other Children's Products With Statutory Exemptions: I agree with staff's assessment that an exemption for the company's ride-on pedal tractor is similar to the statutory exemption for metal component parts of bicycles and related products. Just as the statutory exemption is narrowly tailored to cover just those parts of a bicycle that cannot meet the 100 ppm lead content limit, our decision is similarly tailored to cover only those component parts of the ride-on tractor for which the 100 ppm standard is too much of a challenge, but 300 ppm is achievable.

Conclusion

I repeat my support for the Commission's decision. I believe that the functional purpose test in P.L. 112-28 represents a thoughtful and measured adjustment to the needs of the market, and I believe that our analysis of Ertl's petition in light of the statute was done appropriately. That said, I caution against too broad an interpretation of our decision. As the Commission found previously, the majority of manufacturers of children's products are able to meet the 100 ppm lead level. For those manufacturers who require higher levels of lead, the functional purpose exception should permit the Commission to grant relief as appropriate. In addition, I suggest that future petitions will be met with quicker Commission action if the petitioners provide actual data in support of the petitions. I also

_

¹⁰ Notwithstanding its statement that lead content up to 100,000 ppm would present a transfer of lead in a wipe test of less than 0.02 micrograms per test, staff in no way indicated that it would approve a request for an exemption for a product with such high lead levels or anything close to that amount.

hope that future Commission consideration of petitions for exemptions will provide us with actual test data rather than theoretical analyses.

Finally, I join my colleagues in noting with approval the unanimity of the vote on this petition, especially given that lead issues have often been vigorously debated over the years.